

## **REMARKS/ARGUMENTS**

Initially, Applicants would like to express appreciation to the Examiner for the detailed Official Action provided.

Upon entry of the above amendments, claim 1 will have been amended, claim 16 will have been canceled without prejudice or disclaimer to the subject matter contained therein, and claim 21 will have been added. Claims 1, 13, 15, 17-19 and 21 are currently pending. Applicants respectfully request reconsideration of the outstanding rejections, and allowance of all the claims pending in the present application.

### ***List of the Rejections under 35 U.S.C. 102 and 103***

In the Official Action, the Examiner rejected claims 1, 13 and 15-17 under 35 U.S.C. 103(a) as being unpatentable over FUKASAWA et al. (EP 0306613);

the Examiner rejected claims 1, 15-17 and 20 under 35 U.S.C. 103(a) as being unpatentable over JP 44-5526; and

the Examiner rejected claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over FUKASAWA in view of KANNO et al. (U.S. Patent No. 4,201,673).

Without acquiescing to the propriety of the Examiner's rejections, Applicants submit that claim 1 has been amended solely in order to expedite prosecution of the presently claimed invention.

In this regard, Applicants submit that none of the applied prior art, alone or in any properly reasoned combination, discloses at least the combination of features recited in independent claim 1.

In particular, amended claim 1 generally sets forth a hollow fiber membrane type fluid treatment device including, inter alia, the treatment liquid inlet and treatment liquid outlet being provided at a circumference of the hollow fiber membrane bundle such that a treatment liquid flows outside of the hollow fiber membranes, the hollow fiber membrane bundle configured to allow waste in the blood to be removed through dialysis utilizing one of a diffusion phenomenon resulting from a concentration gradient and filtration resulting from a pressure gradient, wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0° and smaller than an angle defined by  $\tan^{-1}\{1/2 \cdot (d_1 - d_4)/L_4\}$  (where,  $d_1$  is the diameter of the hollow fiber membrane bundle at an end face of the resin layer,  $d_4$  is an inner diameter of the body straight portion or minimum diameter portion of the housing body portion, and  $L_4$  is the length (one side) of the end tapered portion which increases in diameter toward the end face of the housing body portion), and wherein a ratio of the length of the body straight portion to the total length of the end tapered portion is 0.7 to 20, and a ratio of the inner diameter of the end tapered portion at the end face of the housing body portion to the inner diameter of the body straight portion is more than 1 and not more than 3.

#### ***Discussion of FUKASAWA***

In setting forth the rejection that relies upon FUKUSAWA, the Examiner asserts, inter alia, that FUKUSAWA discloses a body straight portion. In particular, the Examiner apparently considers the straight portions on the inner surface, near ports 27 and 28 in FUKUSAWA, to be equivalent to the presently claimed body straight portion. (See comments in Page 3, lines 1-5 of the Official Action).

Contrary to the Examiner's assertions, Applicants submit that FUKUSAWA is very differently structurally from the presently claimed invention.

More specifically, Applicants submit that in FUKUSAWA the tapered structure is provided in the center of the device; therefore, the density of the hollow fiber membrane is increased in the center part of the device. That is, in FUKUSAWA the tapered structure is provided to vary the flow speed in the longitudinal direction (i.e., along the axis of the bundle) in order to promote a turbulent flow condition, thereby improving gas exchange efficiency (i.e., the exchange rate between oxygen and blood). [See page 5, lines 23-35 in FUKUSAWA]. More simply put, Applicants submit that the tapered portion in FUKUSAWA causes a turbulent (or random) flow in the device.

This is in direct contrast to the presently claimed invention in which the tapered portion is provided at opposing ends of the housing body portion to make the treatment liquid flow uniformly between the hollow fiber membrane bundle. Further, the body straight portion of the presently claimed invention provides the fluid treatment device with a region in which uniform delivery of the treatment liquid and the blood (i.e., the liquid to be treated) that flows within the hollow fiber membrane to enable an efficient exchange of substances (e.g., wastes, liquids, etc.) through, e.g., a diffusion phenomenon or filtration. More simply put, Applicants submit that the presently claimed invention provides a uniform flow in the fluid treatment device.

Accordingly, Applicants submit that FUKUSAWA (in fact) teaches against the presently claimed body straight portion. As discussed supra, FUKUSAWA discloses providing a tapered portion in the center of the device to cause turbulent flow. Therefore, Applicants submit that modifying FUKUSAWA to include the presently claimed body straight portion (*which is in a center of the housing body portion*) would destroy the object of the invention in FUKUSAWA,

i.e., since such a modification would eliminate random (*or turbulent*) flow in the device of FUKUSAWA; thereby, destroying the preferable gas exchange rate that is obtained due to the presence of the tapered center portion in FUKUSAWA.

Thus, Applicants submit that FUKUSAWA, alone or in any properly reasoned combination, fails to disclose at least the presently claimed body straight portion in a center of the housing body portion and an end tapered portion provided at opposing ends of the housing body portion, the end tapered portion increasing in diameter toward an end face of the housing body portion; much less, a ratio of the length of the body straight portion to the total length of the end tapered portion is 0.7 to 20, and a ratio of the inner diameter of the end tapered portion at the end face of the housing body portion to the inner diameter of the body straight portion being more than 1 and not more than 3 (i.e., since FUKUSAWA doesn't even contemplate the presently claimed straight body portion), as generally recited in amended claim 1.

Further, Applicants submit that FUKUSAWA is directed towards an artificial lung in which oxygen flows within the hollow fiber membranes and blood flows outside of the hollow fiber membranes. Accordingly, in FUKUSAWA oxygen passes through the hollow fiber membranes from an inside to an outside of the hollow fiber membranes in order to provide oxygen to the blood which *always* flows outside of the hollow fiber membranes.

In the presently claimed invention, Applicants submit that the blood (which flows within the hollow fiber membranes) is purified by removing waste through the hollow fiber membranes (and some liquid components) from an inside to an outside of the hollow fiber membranes by utilizing a diffusion phenomenon between liquids or filtration caused by a pressure gradient. Further, in the presently claimed invention the liquid components may also pass from the outside to the inside of the hollow fiber membranes. In other words, the liquid components in the

present invention can flow from either side (i.e., outside or insider) of the hollow fiber membranes.

Additionally, Applicants submit that one of ordinary skill in the art would not expect to be able to utilize an artificial lung, having hollow fiber membranes structured to allow a passage of oxygen from an inside to an outside of the hollow fiber membrane (while restricting blood to the outside of the hollow fiber membrane), in a fluid treatment device that removes waste (and liquids) from blood.

Thus, Applicants submits that FUKUSAWA, alone or in any properly reasoned combination, does not disclose the presently claimed hollow fiber membrane bundle configured to allow waste in the blood to be removed through dialysis utilizing one of a diffusion phenomenon resulting from a concentration gradient and a filtration phenomenon resulting from a pressure gradient, as generally recited in claim 1.

#### ***Discussion of JP 44-5526***

Further, Applicants submit that the presently claimed invention is very different structurally from the device in JP '526.

In particular, Applicants submit that JP '526 apparently discloses that the hollow fiber membranes being bundled together within flexible sleeves and maintained in close contact. Thus, in JP '526 the sleeves are disposed near the end portion so that the distance between the sleeves increase. In other words, Applicants submit that JP '526 does not disclose the distance between individual hollow fiber membranes increasing, but rather (at best) the distances between bundled membranes increasing.

Accordingly, because the number of bundles are much less than the number of hollow fiber membranes in JP '526, Applicants submit that the tapered portion in JP '526 will not provide the same advantageous total effect of the presently claimed invention. In other words, Applicants submit that the presently claimed invention allows a distance between individual hollow fiber membranes to gradually increase toward the end face.

***RE: FUKASAWA and JP 44-5526***

In setting forth the rejections of claim 16, the Examiner acknowledges that both FUKUSAWA and JP 44-5526 do not disclose a ratio of the length of the body straight portion to the total length of the end tapered portion being 0.7 to 20, and a ratio of the inner diameter of the end tapered portion at the end face of the housing body portion to the inner diameter of the body straight portion being more than 1 and not more than 3, as generally recited in claim 1.

Nevertheless, the Examiner asserts that, since the instant application is silent to as to unexpected results, it would have been obvious to one of ordinary skill in the art to change the length of the tapered and straight portions because such a modification merely involves a change in size or dimension of a component (see pages 5 and 9 of the Official Action).

Initially, as discussed supra, Applicants note that FUKUSAWA does not disclose the presently claimed body straight portion, and therefore cannot possibly contemplate the aforementioned ratio.

Additionally, both FUKUSAWA and JP 44-5526 fail to disclose or contemplate any unexpected results that may result from a tapered portion in the devices.

To the contrary, Applicants submit that the unexpected results and critically of the end tapered portion of the presently claimed invention is clear from a review of the present Disclosure.

In this regard, the present Disclosure clearly explains that, as to the body straight portion of the housing body portion, “it is preferable that the ratio ((L2-L4)/L4) of the length of the body straight portion to the length of the end tapered portion be 0.7 to 20. If the ratio of the length of the straight portion to the length of the end tapered portion is smaller than 0.7, a slight short-path of the dialysate may occur, whereby the removal performance may be insufficient. If the ratio is greater than 20, since the length of the end tapered portion in comparison with the length of the straight portion may be short, a short-path may also occur.” (See page 21, lines 10-17 of the present Disclosure.)

More simply put, Applicants submit that the Disclosure clearly explains that, by selecting the ratio to be within the aforementioned range, sufficient removal performance may be maintained in the presently claimed invention. As discussed supra, this is in direct contrast to the applied prior art, which does not disclose or contemplate, e.g., that any undesirable effect may result from a particular taper.

Similarly, Applicants submits that there is nothing in the disclosure of FUKASAWA and JP 44-5526 that can reasonably be considered to contemplate or suggest a relationship between selecting an upper limit of the angle (i.e.,  $\tan^{-1}\{1/2 \cdot (d_1-d_4)/L_4\}$ ) based upon the diameter of the hollow fiber membrane bundle, an inner diameter of the straight body portion, and the length (one side) of the end tapered portion.

As a result of the aforementioned features, Applicants submit that the substance removal performance is significantly increased, and the variation in the substance removal performance is

little, and occurrence of leakage due to breakage of the hollow fiber membrane is significantly reduced depending on the diameter-expanding portion. (See paragraph on page 33 of the present Disclosure). As discussed supra, Applicants submit that the applied prior art does not disclose or contemplate, e.g., that an undesirable short-path may result from a particular taper or a tapered portion.

Thus, Applicants submit that both FUKASAWA and JP 44-5526, alone or in any properly reasoned combination, fails to disclose at least the presently claimed angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion being greater than 0° and smaller than an angle defined by  $\tan^{-1}\{1/2 \cdot (d_1 - d_4)/L_4\}$  (where,  $d_1$  is the diameter of the hollow fiber membrane bundle at an end face of the resin layer,  $d_4$  is an inner diameter of the body straight portion or minimum diameter portion of the housing body portion, and  $L_4$  is the length (one side) of the end tapered portion which increases in diameter toward the end face of the housing body portion), and wherein a ratio of the length of the body straight portion to the total length of the end tapered portion is 0.7 to 20, and a ratio of the inner diameter of the end tapered portion at the end face of the housing body portion to the inner diameter of the body straight portion is more than 1 and not more than 3, as generally recited in claim 1.

Additionally, Applicants also expressly incorporate all other arguments made in Applicants' previous Responses.

***Generally***

Accordingly, Applicants submit that the rejections of claims 1 and 13 and 15-20 under 35 U.S.C. §103 are improper and should be withdrawn.

In view of the arguments herein, Applicants submit that independent claim 1 is in condition for allowance. With regard to dependent claims 13, 15, 17-19 and 21, Applicants assert that these claims are allowable on their own merit, as well as because they depend from independent claim 1 which Applicants have shown to be allowable.

Thus, it is respectfully submitted that all of the claims in the present application are clearly patentable over the references cited by the Examiner, either alone or in combination, and an indication to such effect is respectfully requested, in due course.

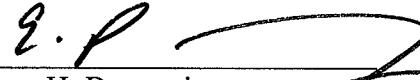
**SUMMARY**

Applicants submit that the present application is in condition for allowance, and respectfully requests an indication to that effect. Applicants have argued the allowability of the claims and pointed out deficiencies of the applied references. Accordingly, reconsideration of the outstanding Official Action and allowance of the present application and all the claims therein are respectfully requested and is now believed to be appropriate.

Applicants submit that this amendment is being made to advance prosecution of the application to allowance and should not be considered as surrendering equivalents of the territory between the claims prior to the present amendment and the amended claims. Further, no acquiescence as to the propriety of the Examiner's rejection is made by the present amendment. All other amendments to the claims which have been made in this amendment, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Should the Examiner have any questions or comments regarding the present response or this application, the Examiner is respectfully invited to contact the undersigned at the below listed number.

Respectfully submitted,  
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